

OCT 09 1987

PRJ. NO. 18H0200/862233

SHEET 1

REPORT ON THE ACUTE DERMAL IRRITATION/CORROSIVITY TO THE INTACT
DORSAL SKIN OF THE WHITE RABBIT BASED ON OECD *

TESTING FACILITY: BASF AKTIENGESELLSCHAFT
DEPARTMENT OF TOXICOLOGY
D-6700 LUDWIGSHAFEN / RHEIN, FRG

AIM OF THE STUDY: ASSESSMENT OF A POSSIBLE IRRITA-
TING OR CORROSIVE POTENTIAL TO
THE SKIN

PROJECT NUMBER: 18H0200/862233

NAME OF TEST SUBSTANCE: 2,4,6-TRIANILINO-P-(CARBO-2'-ETHYL-HEXYL**
-1'-OXI)-1,3,5-TRIAZINE

LOT NUMBER: 18301/142

DEGREE OF PURITY: 98 %

PHYSICAL STATE/APPEARANCE: POWDER, WHITE

HOMOGENEITY OF THE TEST SUBSTANCE: PROVIDED BY SHAKING THE TEST SUBSTANCE

STORAGE STABILITY
AT ABOUT 8 DEGREE CELSIUS: ON COMPLETION OF ALL TESTS THE STABILITY
OF THE TEST SUBSTANCE WILL BE VERIFIED
BY A REPEATED ANALYSIS. THE RESULT CAN
BE OBTAINED FROM THE SPONSOR (ME/Z).

STABILITY OF THE TEST SUB-
STANCE PREPARATION(S): THE STABILITY OF THE TEST SUBSTANCE IN
AQUA DEST. WAS CONFIRMED BY ANALYSIS.

HOMOGENEITY OF THE TEST SUBSTANCE
PREPARATION(S): PROVIDED BY STIRRING OR GRINDING THE SUBSTANCE
PREPARATION.

Hildebrand. 9.5.87
DR. MED. VET. HILDEBRAND
(HEAD OF EXPERIMENTAL TOXICOLOGY)

Kirsch Oct-6, 1987
DR. MED. VET. KIRSCH
(STUDY DIRECTOR)

* METHOD AND ASSESSMENT BASED ON OECD GUIDELINE (404) FOR
TESTING OF CHEMICALS ADOPTED MAY 12TH, 1981

** DETAILED INFORMATION ON THE CHARACTERIZATION OF THE TEST SUBSTANCE
IS INCLUDED IN THE RAW DATA

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BE COMMUNICATED TO THIRD PERSONS, REPRODUCED, OR PUBLISHED IN ANY
FORM EXCEPT WITH THE PROPRIETOR'S EXPLICIT PERMISSION.

THIS REPORT CONSISTS OF 7 PAGES.

ACUTE SKIN IRRITATION/CORROSIVITY (OECD)
.....METHOD
.....

ANIMAL SPECIES: RABBIT/WHITE VIENNA

ANIMAL BREEDER: GAUKLER; D-6050 OFFENBACH/MAIN, FRG

TYPE OF CAGE: CAGE MADE OF STAINLESS STEEL
WITH WIRE MESH WALK FLOORS,
FLOOR AREA: 40 CM X 51 CM

NO. OF ANIMALS PER CAGE: 1

ANIMAL IDENTIFICATION: EAR TATTOO (= ANIMAL NO.)

ROOM TEMPERATURE/
RELATIVE HUMIDITY: THE ANIMALS WERE HOUSED IN FULLY
AIR-CONDITIONED ROOMS. CENTRAL
AIR-CONDITIONING GUARANTEED A
RANGE OF 20 - 24 DEGREES CELSIUS
FOR TEMPERATURE AND OF 30 - 70%
FOR RELATIVE HUMIDITY. THERE
WERE NO DEVIATIONS FROM THESE
RANGES WHICH INFLUENCED THE RE-
SULTS OF THE STUDY.

DAY/NIGHT RHYTHM: 12 H/12 H (6.00 - 18.00 HOURS/
18.00 - 6.00 HOURS)

BEDDING: NO BEDDING IN THE CAGES; SAW-
DUST IN THE WASTE TRAYS

DIET: KLIBA 341, 4 MM;
FIRMA KLINGENTALMUEHLE AG
CH-4303 KAISERAUGST, SWITZERLAND
(ABOUT 130 G PER ANIMAL PER DAY)

FEED ANALYSIS: THE FEED USED IN THE STUDY WAS AS-
SAYED FOR CONTAMINANTS. IN VIEW OF
THE AIM AND DURATION OF THE STUDY
THE CONTAMINANTS OCCURING IN COM-
MERCIAL FEED OUGHT NOT TO INFLUENCE
THE RESULTS.

DRINKING WATER: ABOUT 250 ML TAP WATER PER
ANIMAL PER DAY

DRINKING WATER ANALYSIS: THE DRINKING WATER IS REGULARLY ASSAYED
FOR CONTAMINANTS BY THE MUNICIPAL
AUTHORITIES OF FRANKENTHAL AND THE
TECHNICAL SERVICES OF BASF AKTIENGE-
SELLSCHAFT. IN VIEW OF THE AIM AND
DURATION OF THE STUDY THERE ARE NO
SPECIAL REQUIREMENTS EXCEEDING THE
SPECIFICATIONS OF THE DRINKING WATER.

ACCLIMATIZATION PERIOD: AT LEAST 8 DAYS BEFORE THE BEGINNING
OF THE STUDY; SAME HOUSING
CONDITIONS AS DURING THE STUDY

CLIPPING OF THE FUR: AT LEAST 15 HOURS BEFORE THE
BEGINNING OF THE STUDY

ACUTE SKIN IRRITATION/CORROSIVITY (OECD)
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WEIGHT DETERMINATION: SHORTLY BEFORE APPLICATION OF THE
TEST SUBSTANCE

EXPOSURE PERIOD: 4 H SEMIOCCCLUSIVE *

NUMBER OF ANIMALS MA: 1

FE: 2

MEAN WEIGHT (KG) MA: 2.50

FE: 2.93

APPLICATION AREA: 2.5 CM X 2.5 CM

FORM OF APPLICATION: 50% AQUEOUS FORMULATION (W/W)

APPLICATION VOLUME: THE TEST PATCH (2.5 CM X 2.5 CM)
WAS COVERED WITH AN ABOUT 0.5 MM
LAYER OF THE 50% SUSPENSION (THUS
ABOUT 0.5 G OF THE SUSPENSION
WAS APPLIED; BECAUSE OF THE NATURAL
MOISTURE OF THE SKIN, DISTILLED
WATER WAS USED TO PREPARE THE SUS-
PENSIONS SO THAT THE TEST HAS BEEN
CARRIED OUT UNDER AS PHYSIOLO-
GICAL CONDITIONS AS POSSIBLE.

APPLICATION SITE: UPPER THIRD OF THE BACK OR FLANKS

REMOVAL OF THE TEST SUBSTANCE: AT THE END OF THE EXPOSURE PERIOD
WITH LUTROL AND LUTROL/WATER (1:1)

OBSERVATION PERIOD: 72 H

READINGS: 30 - 60 MINUTES AFTER REMOVAL
OF THE TEST PATCHES AND
24 H, 48 H, 72 H,
AFTER THE BEGINNING OF APPLICATION

NEGATIVE CONTROL: UNTREATED SKIN SITES OF THE
SAME ANIMAL

* TEST PATCHES WERE SECURED IN POSITION WITH A POROUS DRESSING
(FOUR LAYERS OF ABSORBENT GAUZE + POROUS BANDAGE).

..... ACUTE SKIN IRRITATION/CORROSIVITY (OECD)

RETENTION OF RECORDS:

THE RAW DATA AS WELL AS THE
ORIGINAL OF THE PROTOCOL AND
THIS REPORT, ARE RETAINED AT
BASF AKTIENGESELLSCHAFT AT LEAST
FOR THE PERIOD OF TIME SPECIFIED
IN THE GLP-REGULATIONS. THE CONDUCT
OF THE STUDY IN CONFORMANCE WITH
GLP WAS MONITORED BY THE QUALITY
ASSURANCE UNIT.

DATA INPUT:

BENZ

DATA CONTROL:

Reimbank Sep. 16. 87

DATE OF APPLICATION:

AUG. 25, 87

RESULTS ACUTE SKIN IRRITATION/CORROSIVITY (OECD)

| | | | |
|--------------|------|------|------|
| ANIMAL | 1 | 2 | 3 |
| ANIMAL NO. | 1019 | 1020 | 0958 |
| A.WEIGHT(KG) | 2.98 | 2.88 | 2.50 |
| SEX | FE | FE | MA |

| READ-INGS | ANI-MAL | INTACT SKIN R | ED SYMPTOMS |
|-----------|---------|---------------|-------------|
|-----------|---------|---------------|-------------|

| | | | |
|-----|---|---|---|
| 4 H | 1 | 0 | 0 |
| | 2 | 0 | 0 |
| | 3 | 0 | 0 |

| | | | |
|------|---|---|---|
| 24 H | 1 | 0 | 0 |
| | 2 | 0 | 0 |
| | 3 | 0 | 0 |

| | | | |
|------|---|---|---|
| 48 H | 1 | 0 | 0 |
| | 2 | 0 | 0 |
| | 3 | 0 | 0 |

| | | | |
|------|---|---|---|
| 72 H | 1 | 0 | 0 |
| | 2 | 0 | 0 |
| | 3 | 0 | 0 |

| | | | |
|----|---|-----|-----|
| ME | 1 | 0.0 | 0.0 |
| ME | 2 | 0.0 | 0.0 |
| ME | 3 | 0.0 | 0.0 |
| ME | | 0.0 | 0.0 |

RESULTS ACUTE SKIN IRRITATION/CORROSIVITY (OECD)

EVALUATION OF ERYTHEMA (R) AND EDEMA (ED):

- 0 = NONE
- 1 = VERY SLIGHT
- 2 = WELL-DEFINED
- 3 = MODERATE TO SEVERE
- 4 = SEVERE TO VERY SEVERE

CALCULATION OF THE MEAN ACCORDING TO 83/467/EEC CRITERIA OF JULY 29TH, 1983
(FOR CALCULATION OF THE MEANS OF ERYTHEMA AND EDEMA ONLY THE READINGS OF 24, 48 AND 72 HOURS ARE USED).

KEY: MA = MALE
FE = FEMALE
H = HOUR
ME = MEAN
W/W = WEIGHT/WEIGHT

BASFAbteilung Toxikologie
Department of Toxicology

Report: Project No.: 18H0200/862233

STATEMENT
OF THE QUALITY ASSURANCE UNIT


Number of test substance: 86/200

Name of test substance: 2,4,6-Triamino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-
1,3,5-triazineTitle: Report on the acute dermal irritation/corrosivity to the intact
dorsal skin on the white rabbit based on OECD

The Quality Assurance Unit performed the inspections given below,
and reported findings to the Study Director and to Management. The
conduct of this short-term study was not inspected; the processes
of the laboratory and of the study involved are inspected in
regular intervals.

| Phase of study/ inspection | Date of inspec- tion | Report to Study Di- rector and to Manage- ment |
|-------------------------------|-------------------------|--|
| Protocol: | Aug.19,1987 | Oct.5,1987 |
| Audit of report: | Oct.5,1987 | Oct.5,1987 |
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Ludwigshafen, Oct.9, 1987


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Dr. rer. nat. H. Fleig
(Head of Quality Assurance Unit)

